REMARKS

A. Priority

The Office Action states that applicant's specific references to the 09/280,181 application should be updated to reflect the fact that the '181 application has issued as U.S. Patent No. 6,280,941. Applicant has amended the specification to reflect this.

B. Information Disclosure Statement

The Office Action states that the IDS filed February 1, 2002 fails to comply with 37 C.F.R. 1.98(a)(2) because copies of reference number 58 (Drake) and foreign patent document FR 2707 011 A were not provided. Applicant has submitted concurrently with the present response a new IDS accompanied by copies of each of these references.

C. Claim rejections – 35 U.S.C. §112, second paragraph

Claims 1-19 are rejected under 35 U.S.C. §112, second paragraph, as indefinite and failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Office Action states that claims 1-9 are indefinite over the recitation of the phrase "wherein said CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, corresponding to nucleotide positions 846 through 869 of (SEQ. ID. NO.:5)" in claim 1. Applicant has amended claim 1 to remove this phrase.

The Office Action states that claim 2 is further indefinite over the recitation of the phrase "wherein said eighteen-fold CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, between nucleotides

845 and 869 of (SEQ. ID. NO.:5)." Applicant has amended claim 2 to remove this phrase.

The Office Action states that claims 9 and 19 are indefinite due to the recitation of the trademarked terms SYBR and YO-PRO. According to the Office Action, the use of these terms renders the claims vague and indefinite. Applicant respectfully asserts that the names in question (SYBR Green I and YO-PRO-1) constitute the only convenient means for identifying these dyes. Further, Applicant asserts that the dyes in question are well known and widely used in the art, making it unlikely that the product associated with these names will change. This is illustrated in part by the fact that both of these names regularly appear in patent claim language. For example, the term SYBR Green I is found in the claim language of U.S. Patent No's. 6,297,014 (Taylor), 6,346,386 (Elenitoba-Johnson), 6,365,341 (Wu), 6,558,929 (Thum), and 6,656,692 (Erikson), while the term YO-PRO-1 is found in the claim language of U.S. Patent No's. 6,297,014 (Taylor), 6,312,930 (Tice), 6,346,386 (Elenitoba-Johnson), 6,472,168 (Matsumoto), and 6,656,692 (Erikson). Based on this, Applicant respectfully asserts that the terms "SYBR Green I" and "YO-PRO-1" constitute the best means for identifying the dyes in question.

The Office Action states that claims 10-11 are indefinite. Applicant has canceled these claims, rendering this rejection moot.

The Office Action states that claims 12-19 are indefinite over the recitation of the phrase "wherein said eighteen-fold CA dinucleotide repeat sequence is located in the genomic sequence upstream from a PARP transcription start site, between nucleotide

positions 845 and 869 of (SEQ. ID. NO.:5)" in claim 12. Applicant has amended claim 12 to remove this phrase.

D. Claim rejections – 35 U.S.C. §103

Claim 10-11 are rejected under 35 U.S.C. §103 as obvious over Fougerousse in view of Ahern. Applicant has canceled claims 10 and 11, rendering this rejection moot.

E. Claim rejections – double patenting

Claims 1-9 and 12-19 are rejected under the judicially created doctrine of obviousness-type double patenting in light of claim 1-4 of U.S. Patent No. 6,280,941 B1 ("the '941 patent"). According to the Office Action, claims 1-9 and 12-19 are not patentably distinct from claims 1-4 of the '941 patent, because they are either anticipated by or obvious over those claims. The Office Action goes on to state that claims 1-9 and 12-19 are generic to all that is recited in claims 1-4, i.e., they are anticipated by claims 1-4. According to the Office Action, both claim sets recite the steps of collecting tissue, amplifying nucleic acids, and detecting amplification products to identify SLE predisposition, and the primers of claims 1-4 from the '941 patent are the same as those of instant dependent claims 5-7 and 15-17.

Applicant respectfully asserts that the present claims are not anticipated by the claims of the '941 patent. The Office Action is correct in stating that both claim sets recite the steps of collecting tissue, amplifying nucleic acids, and detecting amplification products to identify SLE predisposition. However, the claim sets differ in how they identify SLE predisposition. Claims 1-4 of the '941 patent utilize two specific primers (SEQ. ID. NO.:1 and SEQ. ID. NO.:2) for amplification. Following amplification, SLE predisposition is determined based only on the size of the amplification products, with

no consideration given to the sequence of those amplification products. The claims of the present invention, on the other hand, identify SLE predisposition based on the nucleotide sequence of the amplification products. Rather than being limited to the use of two specific primers, this method allows the use of any primer set that amplifies the region between D1S2860 and D1S213. Following amplification, amplification products are analyzed for the presence of either a twelve-fold or an eighteen-fold CA dinucleotide repeat. This method allows for a more precise determination of SLE susceptibility using a wider range of amplification primers. As such, the claims of the present invention are not anticipated by claims 1-4 of the '941 patent.

Claims 10-11 are rejected under the judicially created doctrine of obviousness-type double patenting. Applicant has canceled claims 10-11, rendering this rejection moot.

CONCLUSION

In view of the foregoing, it is submitted that the present claims are in condition for allowance. Accordingly, Applicant respectfully requests that a Notice of Allowance be issued.

Respectfully submitted,
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Date: 12/6/04

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 11/3/04 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required. **Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted.** 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
- ☐ B. New paragraph(s) should not be underlined.
- ☐ C. Other ______

☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
- ☐ B. Other ______

☐ 3. Amendments to the drawings: ______

☑ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
- ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
- ☑ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following 7 status identifiers: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New) and (Not entered).
- ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
- ☐ E. Other: ______

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT,** applicant is given ONE MONTH from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and **this ONE MONTH time limit is not extendable.**

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION (including a submission for an RCE),** and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION,** this form may be an attachment to an Advisory Action. **<u>The period for response to a final rejection continues to run from the date set in the final rejection</u>,** and is not affected by the non-compliant status of the amendment.

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